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COMPLIANCE POLICY GUIDE

PHARMACIST-IN-CHARGE AT A DRUG MANUFACTURER

32-1961. Limitation on manufacture and sale of drugs

A. It is unlawful for any person to manufacture, compound, sell or dispense any drugs or to dispense or compound the prescription orders of a medical practitioner, unless he is a pharmacist or a pharmacy intern acting under the direct supervision of a pharmacist, except as provided in section 32-1921. This subsection does not prevent a pharmacy technician or support personnel from assisting in the dispensing of drugs if this is done pursuant to rules adopted by the board and under the direct supervision of a licensed pharmacist.

R4-23-604. Resident Drug Manufacturer

H. Manufacturing and distribution.

1. A drug manufacturer permittee shall manufacture and distribute a drug only:

d. Under the supervision of an Arizona Board-licensed pharmacist as required in A.R.S. § 32-1961. Manufacturing processes that require the supervision of a pharmacist include weighing, mixing, compounding, tableting, packaging, and labeling.

J. A drug manufacturer permittee shall:

2. Ensure that an Arizona Board-licensed pharmacist is present at the facility whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled.

BACKGROUND: Board statute and rules require a manufacturer to employ an Arizona-licensed pharmacist as the pharmacist-in-charge to oversee the manufacturing process and further state that an Arizona-licensed pharmacist shall be present at the facility whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled. The Board staff has always enforced this requirement and further has required a manufacturer to employ an Arizona-licensed pharmacist a minimum of 40 hour per week, unless the manufacturer can show that manufacturing, packaging, repackaging, labeling, or relabeling occurs less frequently than 40 hours per week. The Board has determined that many manufacturers now operate their facilities 24 hours a day, seven days a week. To comply with a strict interpretation of Board statute and rules, those manufacturers must employ a pharmacist 24/7. To date in such instances, the Board staff has required that a pharmacist be employed a minimum of 40 hours per week and allowed processing to occur 24/7 if all processes are reviewed and checked by a pharmacist before release of any product from the facility.

GOAL: To provide a guide to manufacturers and pharmacists of the Board's interpretation of A.R.S. 32-1961(A) and A.A.C. R4-23-604(H)(1)(d) and (J)(2), specifically how many hours per week a pharmacist should be employed when the manufacturing process occurs 24/7.

POLICY:

1. It is the Board's position that with the automation and other improved technologies used by today's manufacturers, the public health and safety would be well served by requiring that each manufacturer employ a pharmacist for a minimum of 40 hours per week with the provision that all manufacturing processes are reviewed and checked by a pharmacist before release of any product from the facility. With this provision, the Board does not believe that requiring a manufacturer to have a pharmacist on site 24/7 is necessary to protect the public health and safety.
2. It is the Board's position that a manufacturer who does not operate the manufacturing process more than 40 hours per week could employ a pharmacist on a part-time basis. For example, a manufacturer who repackages drugs for four hours a day, five days a week would only need to employ a pharmacist for

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those four hours per day for five days a week when actual manufacturing, packaging, repackaging, labeling, or relabeling occurs.